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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Start-Up Option License: Potent and Selective Analogues of

Monamine Transporters; Methods of Making; and Uses Thereof

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is a notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National

Institute of Drug Abuse, National Institutes of Health, Department of Health and Human Services is

contemplating the grant of an exclusive start-up option license to practice the inventions embodied in the

following Patent Applications and all related continuing and foreign patents/patent applications for the

technology family to EncepHeal Therapeutics, Inc., located in Winston-Salem, North Carolina.

DATES: Only written comments and/or applications for a license which are received by the NCI

Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION

IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials

relating to the contemplated exclusive license should be directed to Martha Lubet, Ph.D., Technology

Transfer Specialist, NCI TTC, 9609 Medical Center Drive, Room IE350, and Rockville, MD 20850.

Telephone: 240 276-5508. Facsimile: 240 276-5505. Email:lubetm@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns analogues of modafinil and methods of

using the analogues for the treatment of substance use disorders and sleep disorders.

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The prospective exclusive start-up option license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive start-up option may be granted unless within fifteen (15) days from the date of this published notice, the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Intellectual Property:

U.S. provisional application 61/774,878, filed March 8, 2013 entitled "Potent and Selective Inhibitors of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-US-01];

PCT application PCT/US2014/021514, filed March 7, 2014 entitled "Potent and Selective Analogues of: Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-PCT-02]; US application 14/772,486, filed September 3, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-US-06]; EPO application 14714043.8, filed September 1, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-EP-05]; Australian application 2014225550, filed September 8, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-AU-03]; Canadian application 2903746, filed September 2, 2015 entitled "Potent and Selective Analogues of Monamine Transporters; Methods of Making; and Uses Thereof" [HHS Ref. No. E-073-2013/0-CA-04];

The patent rights to these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive start-up option licensed territory may be worldwide and the field of use may be limited to: a) treatment of substance use disorders and/or b) treatment of sleep disorders.

Upon the expiration or termination of the exclusive start-up option license, EncepHeal

Therapeutics, Inc. will have the exclusive right to execute a start-up exclusive commercialization license

which will supersede and replace the exclusive start-up option license with no greater field of use and

territory than granted in the exclusive start-up option license.

Dated: December 17, 2015.

Richard U. Rodriguez,

Associate Director

Technology Transfer Center

National Cancer Institute

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